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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/534,773	ROBERTSON ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Lack of Unity Restriction/Election of Species

1. Claims 1-38 are all the pending claims for this application and subject to lack of unity restriction/election of species requirement.

2. Claims 3-9, 12, 14, 15, 18, 19, 36 and 37 as "use" claims are directed to non-statutory subject matter under 35 U.S.C. 101 (MPEP 2173.05(q)). Applicants will need to amend or delete the claims in response to this Office Action. To advance prosecution, Claims 3-9, 12, 14, 15 and 18 have been interpreted in light of the specification and restricted as below. The intended subject matter for Claims 19, 36 and 37 is unclear and the claims have been withdrawn from restriction.

3. Claims 12, 14-18 and 27-35 are improper multiple dependent claims because each of the claims depends from a multiple dependent claim (MPEP 37 C.F.R. 1.75(c)). Applicants are invited to bring the claims into proper dependency in their response.

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claims 1-38 is an immunoassay using a tumor marker protein in detecting an immune response. The disclosure of the following references read on the claims:

Robertson et al. (WO 99/58978; published November 18, 1999; filed May 11, 1999) discloses methods for detecting immune responses to tumor marker proteins using an immunoassay to test a sample for an immune response (see Claims 1-72).

Luo et al. (British J. Cancer 87:339-343 (2002)) discloses screening autoantibodies against heat shock protein 90 in various cancer sera (Table 2; Fig. 2) with an immunoassay (p. 340, Col. 1, ¶3).

The references anticipate the claimed invention. Therefore the technical feature recited in claims 1-38 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s)1-8 and 11-18, drawn to a method for detecting cancer-associated anti-tumor autoantibodies using a tumor marker protein based-immunoassay where the presence of the autoantibody can be used to detect or diagnose a cancer, monitor the progress of a cancer, detect or screen a cancer in an asymptomatic patient, monitor the response to an anti-cancer treatment, and detect the recurrence of a cancer.

Group II, claim(s), 9 and 10, drawn to a method of screening an anti-cancer vaccine and a method of monitoring an immune response to an anti-cancer vaccine comprising an immunoassay for the detection of cancer-associated anti-tumor autoantibodies.

Group III, claim(s) 20-31, drawn to methods for preparing a tumor marker protein.

Group IV, claim(s) 32-35, drawn to a preparation comprising a tumor marker protein and a kit for an immunoassay comprising a tumor marker protein immobilized to a solid support.

Group V, claim(s) 38, drawn to a method for calibrating an assay for measurement or detection of a tumor marker protein.

6. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Robertson et al. and Luo et al. the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claims 1-38 is not special.

The inventions are distinct and related for the following reasons:

7. The methods of Groups I-III and V differ in the method objectives, method steps and parameters, intended populations and in the reagents used. The method of Group I requires performing an immunoassay on a sample obtained from a subject where the immunoassay requires a tumor-specific protein, and the immunoassay requires the detection of a tumor-specific autoantibody in order to detect or diagnose a cancer, monitor the progress of a cancer, detect or screen a cancer in an asymptomatic patient, monitor the response to an anti-cancer treatment, and detect the recurrence of a cancer. The method of Group II requires administering an anti-cancer vaccine to a patient in order to determine whether the vaccine elicits an immune response where the

immune response is measured in an immunoassay comprising a tumor marker protein. The method of Group III requires isolating a tumor marker protein from a body fluid or excretion in order to prepare the protein. The method of Group V requires a tumor marker protein, a spectrophotometer and/or an antibody reagent to a tumor marker protein in order to perform a calibration on an assay used for measuring or detecting a tumor marker protein. The examination of all groups would require different, non-coextenisve searches in the U.S. and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus methods of Groups I-III and V are separate and distinct in having different method steps, different intended populations and different endpoints and are patentably distinct.

8. Inventions of Group IV and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used to make a materially different product such as any non-tumorigenic protein. As for the tumor marker protein, it can be prepared/isolated by gel filtration methods known in the art or by synthetic biochemistry if the structure is known. The examination of all groups would require different, non-coextenisve searches in the U.S. and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus inventions of Group IV and Group III are separate and distinct and are patentably distinct.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

11. If Group II is elected, then species (immunogenic preparation) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) tumour marker protein or an antigenic fragment thereof

Specie B) nucleic acid sequence expressing said tumour marker protein

Species A and B are related but distinct molecules. In the instant case, the nucleic acid does not overlap the scope of the protein and vice versa as evidence by the distinct structures and functions. A nucleic acid structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein while a protein's function is variable, and in this case, to be antigenic. Additionally, the nucleic acid and proteins are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the nucleic acid and protein have materially different functions as noted above.

Because these species are distinct for the reasons given above and the search required for a nucleic acid is not required for a protein, speciation for examination purposes as indicated is proper. To search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims drawn to proteins must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated proteins are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the DNA sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, species A and B have been appropriately speciated on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 10 is generic as to species A and B.

12. If Groups I, II or III are elected, then species (tumor marker protein) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) MUC1

Specie B) MUC16

Specie C) c-myc

Specie D) c-erbB2

Specie E) p53

Specie F) ras

Specie G) BRCA1

Specie H) BRCA2

Specie I) APC

Species J) PSA

Specie K) CEA

Specie L) CA19.9

Species A-L are distinct and unrelated tumor antigens, each well recognized in the art as being expressed on different cell types, having different structural proteins, different cognate ligands and signal interactions. Any commercial database of proteins lists this information. In addition, the Human Protein Reference Database (HPRD.org)

describes the tissue expression patterns, structural and functional properties and any disease correlates for the tumor antigens of species A-L. The species are not obvious variants or overlapping, thus to search the species together would present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 10, 20 and 25 are generic as to species A-L.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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